



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2016-0027]

Statements That Bioengineered or Genetically Modified (GM)
Ingredients or Animal Feed Were not Used in the Production of
Meat, Poultry, or Egg Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and opportunity for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is
announcing the availability of the Agency's compliance guidance
on how companies can make label or labeling claims concerning
the fact that bioengineered or genetically modified (GM)
ingredients or animal feed were not used in the production of
meat, poultry, or egg products. For purposes of this guidance
document, these claims will be referred to as "negative claims."

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER
DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: A downloadable version of the compliance guidance is
available to view and print at

[http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-](http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/claims-guidance/procedures-nongenetically-)
[compliance/labeling/claims-guidance/procedures-nongenetically-](http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/claims-guidance/procedures-nongenetically-)

engineered-statement. No hard copies of the compliance guidance have been published.

FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov/>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name, docket number FSIS-2016-0027, and the document title: Statements that Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were not Used in the Production of Meat, Poultry, or Egg Products.

Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

For additional information about FSIS labeling policies and programs, including Generic Label Approval, please review the FSIS Web Site at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/> or contact the Labeling and Program Delivery Staff at (301) 504-0878 or (301) 504-0879.

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 164-A, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel L. Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

FSIS is the public health regulatory agency in the USDA that is responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome,

and accurately labeled and packaged. FSIS develops and implements regulations and policies to ensure that meat, poultry, and egg product labeling is not false or misleading. Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601-695, at 607), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451-470, at 457), and the Egg Products Inspection Act (21 U.S.C. 1031-1056, at 1036) the labels of meat, poultry, and egg products must be approved by the Secretary of Agriculture, who has delegated this authority to FSIS, before these products can enter commerce.

Compliance Guide

FSIS is announcing that it has developed a compliance guide for companies that seek to make label or labeling claims concerning the fact that bioengineered or GM ingredients were not used in a meat, poultry or egg product. This guidance also provides information on how companies can make label or labeling claims that a product was produced from livestock or poultry that were not fed bioengineered or GM feed. For purposes of this guidance document, these claims will be referred to as "negative claims."

FSIS has approved negative claims through its prior label approval process. Because FSIS does not have the ability to

independently verify negative claims for ingredients or feed, FSIS has required establishments that make these claims to comply with standards established by a third-party certifying organization. FSIS currently requires that the third-party certifying organization's standards be publicly available on a web site and the label or labeling disclose the web site address of the third-party certifying organization. FSIS currently requires that the establishment demonstrate that its claims of third-party certification are truthful and not misleading.

As a policy matter, prior to issuing this guidance document, FSIS has not allowed the use of the terms "genetically modified organism" or "GMO" in negative claims. FSIS has allowed the use of the terms "genetically modified organism" or "GMO" on product labels or labeling only if the name of the third-party certifying organization contains these terms (e.g. "Non-GMO Project"). However, recent legislation was enacted (Pub. L. 114-216) requiring the Secretary of Agriculture to develop and implement a mandatory national bioengineered food disclosure standard within 2 years. This legislation also addresses negative claims, providing that "a food may not be considered to be 'not bioengineered' or 'non-GMO', or any other similar claim describing the absence of bioengineering in the

food solely because the food is not required to bear a disclosure that the food is bioengineered under this subtitle.” (Pub. L. 114-216, section 294(c)). Therefore, FSIS has reconsidered its position and will allow the use of the terms “genetically modified organism” or “GMO” in negative claims provided that the label or labeling is otherwise truthful and not misleading.

Effective immediately, FSIS will begin approving negative claims for meat, poultry and egg products that do not contain bioengineered ingredients or that are derived from livestock that do not consume bioengineered feed and that contain the terms “genetically modified organism” or “GMO”. In evaluating such claims, FSIS will utilize the definition of “bioengineering” in Pub. L. 114-216. In that law, the term “bioengineering” refers to a food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.

Consistent with past practice, FSIS will continue to allow the use of synonymous terms such as “genetically engineered.” If FSIS has approved an organic claim on the product label,

establishments may add an applicable negative claim of the kind discussed in the guidance.

FSIS encourages companies to follow this guidance. This guidance represents FSIS's current thinking, and FSIS welcomes comment on this compliance guidance and will update it as necessary to reflect comments received and any additional information that becomes available.

USDA Nondiscrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination, any person in the United States under any program or activity conducted by the USDA.

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at:

http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/federal-register-notices>.

FSIS also will make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings,

recalls, and other types of information that could affect or would be of interest to constituents and stakeholders. The update is communicated via Listserv, a free electronic mail subscription service for industry, trade and farm groups, consumer interest groups, allied health professionals, and other individuals who have asked to be included. The update is available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves and have the option to password protect their account.

Done at Washington, DC on August 19, 2016.

Alfred V. Almanza,

Acting Administrator.

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